

# EXHIBIT 3

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PLEXXIKON INC.

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF CALIFORNIA  
OAKLAND DIVISION

PLEXXIKON INC.,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS  
CORPORATION,

Defendant.

Case No. 4:17-cv-04405-HSG

**PLAINTIFF PLEXXIKON, INC.'S DAMAGES  
CONTENTIONS**

Ctrm: 2 – 4th Floor

Judge: Honorable Haywood S. Gilliam, Jr.

1 Plaintiff Plexxikon, Inc. (“Plexxikon”) provides the following disclosure of its damages  
2 contentions pursuant to Northern District of California Patent Local Rule 3-8.

3 As an initial matter, this case is still early in discovery and Defendant Novartis Pharmaceuticals  
4 Corporation (“Novartis”) has not produced numerous categories of requested documents which would be  
5 relevant to a damages calculation. For these reasons, Plexxikon’s damages contentions are inherently  
6 preliminary, and likely to change as discovery moves forward. Plexxikon therefore intends to update  
7 these contentions after it has obtained the information necessary to make a more fulsome calculation of  
8 its damages.

9 Plexxikon is currently seeking the following categories of damages, although it may choose to  
10 present only some of these theories in its expert report and trial, and it may add additional theories  
11 insofar as discovery reveals them.

## 12 **I. REASONABLE ROYALTY**

### 13 **A. Factual Background**

14 Plexxikon is seeking a reasonable royalty based on the legal theory that damages in a patent case  
15 may be no less than a reasonable royalty. *See* 35 U.S.C. § 284.

16 The accused products in this case include dabrafenib, sold by Defendant Novartis  
17 Pharmaceuticals Corporation (“Novartis”) under the trade name Tafenlar®.<sup>1</sup> Novartis bought Tafenlar®  
18 from GlaxoSmithKline (GSK) in 2015. Tafenlar® competes with vemurafenib, sold under the trade  
19 name Zelboraf®, a drug developed by Plexxikon. Zelboraf® began clinical trials in 2006 and gained  
20 FDA approval for the treatment of unresectable or metastatic melanoma with the BRAF(V600E)  
21 mutation in 2011. Tafenlar® and Zelboraf® are the only two products in a class of anti-cancer drugs  
22 known as “selective BRAF kinase inhibitors,” which Plexxikon’s scientists discovered at least as early as  
23 2005. In 2013, two years after Zelboraf® was approved, the FDA approved Tafenlar® for the treatment  
24 of patients with unresectable or metastatic melanoma with the BRAF(V600E) mutation.

25  
26  
27 <sup>1</sup> Novartis has not produced discovery on whether it makes, uses, sells, offers for sale, or imports other  
28 compounds covered by the Patents-in-Suit. As such, Plexxikon’s damages contentions are currently  
limited to Tafenlar® and the combination therapies that it forms a part of, but Plexxikon reserves the  
right to amend its contentions to capture additional compounds.

1 Both Tafenlar® and Zelboraf® are also sold as part of combination therapies with another class of  
2 anti-melanoma drugs known as MEK inhibitors. The combination of a BRAF inhibitor and a MEK  
3 inhibitor increases the efficacy of the treatment compared to the BRAF inhibitor and MEK inhibitor  
4 being prescribed individually. Tafenlar® is sold in combination with a MEK inhibitor called Mekinist®,  
5 while Zelboraf® is sold in combination with Cotellic®.

6 Plexxikon contends that the royalty base for the composition of matter claims is based on all of  
7 the sales of Tafenlar® (a) in the United States and (b) internationally, insofar as the active ingredient or  
8 the final product was exported from the United States. Because Novartis has not yet produced  
9 information showing either the total amount of these sales, or the unit counts associated with these sales,  
10 Plexxikon is currently unable to calculate the royalty base.

11 Plexxikon contends that the royalty base for the treatment claims should also be based on the  
12 retail price of Tafenlar® *to patients* who are treated with the accused product. Plexxikon does not yet  
13 have data on the average retail price of Tafenlar® to patients. For that reason as well, Plexxikon is  
14 unable to calculate the royalty base for its damages.

15 Plexxikon also contends that a reasonable royalty rate should be determined by looking at  
16 comparable licenses, in light of the *Georgia-Pacific* factors. *See Uniloc USA, Inc. v. Microsoft Corp.*,  
17 632 F.3d 1292, 1317 (Fed. Cir. 2011).

18 On September 28, 2006, Plexxikon entered into a Collaboration with Hoffman-La Roche Inc. and  
19 F. Hoffman-La Roche Ltd. (collectively, “Roche”) (“2006 Roche Agreement”). As part of that  
20 agreement, Plexxikon and Roche agreed to a collaboration pursuant to which [REDACTED]

21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]  
26 [REDACTED]  
27 [REDACTED]  
28 [REDACTED]

\_\_\_\_\_

[illegible][illegible]

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[illegible]

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[REDACTED]

[REDACTED]

In August 2011, Roche launched vemurafenib under the trade name Zelboraf®, and began paying royalties to Plexxikon per terms of the 2006 Roche Agreement. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**B. Factors Evidencing a Reasonable Royalty**

Plexxikon contends that its license agreements with Roche provide a *floor* for what a reasonable royalty would be. A reasonable royalty can be calculated by positing a “hypothetical negotiation” between a willing licensor and a willing licensee to ascertain the royalty upon which the parties would have agreed had they successfully negotiated an agreement just before the infringement began. *See Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 807 F.3d 1283, 1303-04 (Fed. Cir. 2015).

In the course of the hypothetical negotiation with Novartis, Plexxikon would have had no reason to accept a royalty rate lower than what it obtained from Roche. [REDACTED]

[REDACTED] are a floor because, among other things, (a) allowing a second competitor (Novartis) into the market would result in a lower volume of sales for Zelboraf® and lower sales prices through price erosion and thus lower royalties earned from the 2006 Roche Agreement, (b) the rates in the 2006 Roche Agreement reflect the fact that Roche agreed to take on expense and risk to enter an unproven market at the time it negotiated rates with Plexxikon, whereas Novartis faced less risk and perhaps less expense because it was able to free ride on Plexxikon’s and Roche’s previous efforts. It is also important to note, that, because the rates in the Roche license agreement are tiered, and because allowing a second competitor into the market would result in Roche making fewer sales (and thus paying Plexxikon at prices corresponding to lower tiers), a reasonable royalty *to Novartis* would need to account for any change in royalty tier under the Roche license expected as a result of licensing Novartis. Plexxikon is currently unable to perform the necessary calculations because it awaits discovery from Novartis, including forecasts, business documents, and testimony from business people, that would allow a determination of the expected competition between the accused product and Roche’s product, as well as the expenses and risks that Novartis and GSK incurred.

The 2006 Roche Agreement is additionally comparable to the hypothetical negotiation because GSK was willing to license the patents that Roche ultimately licensed for the exact same royalty rates, but with slightly different business terms. The fact that GSK independently offered to license an analogous patent for the same rates shown in the 2006 Roche Agreement, and the fact that GSK created the infringing product is further evidence on which Plexxikon will rely to establish that the rates shown in the Novartis license are a floor.

Another relevant data point of which Plexxikon is currently aware is the amount Novartis paid to acquire various assets from GSK. The documents Novartis has produced to date, show that Novartis allocated approximately \$2.24 billion as the price paid for Tafenlar®. Given that Novartis paid a substantial sum to obtain the accused product, Novartis likely expected the accused product to be quite profitable. This underscores the losses that Zelboraf® would be expected to take as a result of Novartis selling a competitive product. Moreover, given substantial profitability, Novartis would have been willing to pay a significant royalty to get a license to the patents-in-suit in the hypothetical negotiation. However, again, Plexxikon cannot undertake an analysis of these issues without discovery from Novartis, including its business documents, forecasts, assessments of the acquisition, and testimony from its business people.

As previously noted, Plexxikon also intends to apply the *Georgia-Pacific* factors in order to determine a reasonable royalty rate. In brief:

1. **Royalties received by the patentee for licensing of the patent-in-suit.** As addressed above, while Plexxikon has not received any money for licensing the patents in suit, it has received money for licensing other patents in the same family covering similar drugs, and will rely on the licenses pursuant to which it licensed those patents.

2. **Rates paid by the licensee for the use of other patents comparable to the patent-in-suit.** For the reasons given above, Novartis' purchase of Tafenlar®, which included rights to GSK's patents, would be considered.

3. **Nature and scope of the license, as exclusive and non-exclusive.** The hypothetical license would be non-exclusive and cover the U.S.

4. **The licensor's established policy to maintain its patent monopoly by not licensing others to use the invention.** Plexxikon intends to introduce evidence to show that it has only licensed one entity, Roche, to make use of the breakthrough that led to the patent, and that is an exclusive license. For the reasons discussed above, Plexxikon would *not* have been willing to license a second market participant without appropriate compensation for the increase in competition that its existing licensee would face.



1           5.       **The commercial relationship between the licensor and the licensee, such as whether**  
2 **they are competitors in the same territory in the same line of business.** Novartis is in effect acting as  
3 a competitor in the marketplace because its accused product competes closely with the Roche product on  
4 which Plexxikon earns royalties. This would tend to suggest a higher royalty rate.

5           6.       **The effect of selling the patented specialty in promoting sales of other products of the**  
6 **licensee; the existing value of the invention to the licensor as a generator of sales of its non-**  
7 **patented items; and the extent of such derivative or convoyed sales.** See below for discussion of  
8 convoyed sales of Mekinist®, which would also tend to support a higher royalty rate.

9           7.       **Duration of patent and term of license.** The patents-in-suit expire in 2028 and therefore  
10 still have substantial life left. Plexxikon intends to argue that it only would have licensed the patents (if  
11 at all) for their full term.

12           8.       **Established profitability of the products made under the patent, its commercial**  
13 **success and its current popularity.** All of these elements point toward a high royalty rate. Plexxikon  
14 will point to the news and scientific press on its invention, the rapid rise of the market share for Novartis'  
15 product, and the continuing popularity of both Plexxikon's and Novartis' products to show that  
16 Plexxikon's scientific invention, and the molecules specifically covered by the patent-in-suit are highly  
17 profitable and popular.

18           9.       **Utility and advantages of patent property over old modes and devices.** Plexxikon will  
19 introduce evidence to show that use of selective BRAF inhibitors fundamentally changed the treatment  
20 for metastatic melanoma and improved treatment for other indications, and had dramatic impacts on life  
21 expectancy. These differences show that the advantages of the patent are substantial, and that a higher  
22 royalty rate is therefore also appropriate.

23           10.      **The nature of the patented invention; the character of the commercial embodiment**  
24 **of it as owned and produced by the licensor; and the benefit of those who have used the invention.**  
25 Plexxikon intends to introduce evidence (including the evidence disclosed in the complaint and in  
26 Plexxikon's discovery responses) to show that the claimed invention is part of Plexxikon's  
27 groundbreaking and game changing invention. The benefit to those who have used the invention –  
28

namely the ability to extend their lives – is also enormously valuable and mitigates in favor of a higher royalty.

11. **The extent to which the infringer has made use of the invention and the value of such use.** Plexxikon contends that Novartis sales on the accused products make use of the invention and that the value of that use encompasses both (a) the financial returns and (b) reputational effects. Plexxikon also intends to seek discovery to determine the extent to which, for example, Novartis is able to amortize its fixed costs over a larger product base as a result of its acquisition of the accused products from GSK, and the benefits that Novartis receives therefrom.

12. **The portion of profit or selling price customarily allowed for the use of the invention.** Plexxikon is not aware of any “customary” profit split used in the pharmaceutical industry.

13. **The portion of realizable profit attributable to the invention as distinguished from nonpatented elements, significant features/improvements added by the infringer, the manufacturing process or business risks.** Plexxikon contends that *all* of the profits from the accused product, after taking into account the development efforts and costs and risks incurred by GSK and Novartis, come from its use of the invention in the asserted patents. As discussed above, however, the costs and risks may have been less for GSK and Novartis than it was for Plexxikon and Roche due to the former’s ability to free ride on the latter’s efforts. There is effectively no value in the fillers and excipients used in the pills. Plexxikon further contends that the accused products have no significant non-infringing features.

14. **Opinion testimony of qualified experts.** Plexxikon intends to offer opinion testimony from qualified experts. Although the full scope of this testimony has not yet been formulated, Plexxikon expects its experts to testify (among other things): (a) the groundbreaking nature of Plexxikon’s invention; (b) the import of the facts discussed in these contentions; (c) an analysis of additional facts produced by Novartis and third parties; and (d) an economic analysis of price erosion.

15. **Outcome from hypothetical arm’s length negotiation at the time of infringement began.** Many of the factors that would go into a hypothetical negotiation (e.g., the fact that allowing a second drug on the market would tend to lower prices and prevent Plexxikon from reaching higher tiers in its agreement with Roche) already have been discussed above. There are, however, other factors as

1 well. For example, as Novartis is aware, Plexxikon has alleged that the known facts imply that GSK  
2 engaged in copying after offering to license Plexxikon's relevant intellectual property, which in turn  
3 would suggest that Plexxikon's discoveries were valuable. Given the early stage of discovery, and  
4 GSK's failure to produce documents, the full scope of GSK's conduct is unknown.

5 **C. Convoyed or collateral sales**

6 Plexxikon contends that Novartis' sales of Mekinist® are, at least in part, convoyed sales. In  
7 particular, Plexxikon contends that the accused product and Mekinist® are "analogous to components of  
8 a single assembly or [are] parts of a complete machine, [and] constitute a functional unit." *Rite-Hite*  
9 *Corp. v. Kelley Co.*, 56 F.3d 1538, 1550 (Fed. Cir. 1995) (en banc); *see also American Seating Co. v.*  
10 *USSC Group, Inc.*, 514 F.3d 1262, 1268 (Fed. Cir. 2008) ("A 'convoyed sale' refers to the relationship  
11 between the sale of a patented product and a functionality associated non-patented product."). In  
12 particular, Mekinist® acts to *extend* the efficacy of the accused product and is far more effective in  
13 combination with a BRAF inhibitor than it is on its own. As a result, some portion of Mekinist® sales  
14 are attributable to the patented technology, since more units of Mekinist® are sold as a result of the  
15 existence of the combination therapy than would be sold if no BRAF inhibitors like Tafenlar® and  
16 Zelboraf® existed. Thus, the patents-in-suit, which cover Tafenlar®, are entitled not only to the royalty  
17 associated with Tafenlar® sales, but also a portion of the revenue associated with Mekinist® sales.

18 Plexxikon intends to introduce evidence as to the science (e.g., how Mekinist® works as part of a  
19 functional unit with the accused product) and its use in the market (i.e., that Mekinist is more effective in  
20 combination with a BRAF inhibitor than on its own) to establish that the accused product drives sales of  
21 the combination therapy.

22 Plexxikon intends to use the convoyed sales of Mekinist® *at least* to help determine the royalty  
23 rate under the *Georgia-Pacific* factors, but may also assert that some of the Mekinist® sales should be  
24 included in the royalty base.

25 Novartis has not yet produced information on its sales of Mekinist®, and it is therefore not  
26 possible to perform a reasonably accurate calculation of this measure of damages.

**D. Additional Information Needed**

In order to provide a fulsome response, Plexxikon needs, in addition to the information mentioned above:

1. Documents indicating whether Tafenlar® is invoiced separately from Mekinist®.
2. Documents indicating whether Zelboraf® is invoiced separately from Cotellic®.
3. Documents relating to Novartis's acquisition of GSK's oncology portfolio, including assessment of the acquisition, due diligence documents, valuations of Tafenlar®, and any evaluation of factors related to Tafenlar®, including analyses related to the determination of the "Reduction Amount" pending clinical outcomes involving Tafenlar®.
4. Forecasts and strategy plans for Tafenlar® and Zelboraf® sales and profits, both alone and in combination with Mekinist® or other drugs.
5. Forecasts and strategy plans for Mekinist®, including the impact on sales with and without combination approval with Tafenlar®.
6. Pricing models for Tafenlar®, Zelboraf®, and Mekinist®.
7. Conjoint studies or surveys of doctors' prescribing habits, including why doctors choose treatments in the relevant market; what clinical outcomes doctors tend to focus on; what other factors like cost, branding, or marketing affect prescribing decisions; if prescribing patterns are different amongst doctors that have prescribed Tafenlar®; if a doctor would prescribe a single agent BRAF or MEK-inhibitor in the absence of a combination; if a doctor would be more likely to prescribe a drug with characteristics most similar to Zelboraf®, Zelboraf®+Cotellic®, Tafenlar®, Mekinist®, or Tafenlar®+Mekinist in the absence of one of the above options.
8. Unit sales, revenues, and prices of Tafenlar®, Mekinist®, and other relevant products over time by indication, including the dosage.
9. Estimates of the percentage of Tafenlar® and Zelboraf® sales that are for metastatic melanoma, and what percentage is used off label.

## II. LOST ROYALTIES

### A. Factors Evidencing Lost Royalties

Tafinlar® and Zelboraf® are the only two drugs in the relevant market – namely the market for selective BRAF kinase inhibitors. Plexxikon therefore contends that lost royalties should be calculated by taking the infringing unit count, undoing the effects of price erosion, and then showing that Roche (Plexxikon’s development partner) would have made most, if not all, of the unit sales that were made by Novartis. From this, one can apply the royalty rates found in Plexxikon’s contract with Roche (adjusted for any erosion of the royalty rates paid to Plexxikon due to Novartis’ infringement) and adjust the amounts for the time value of money to obtain Plexxikon’s lost royalties. To perform this calculation in a reasonably accurate way, Plexxikon needs discovery from Novartis, including the financial data it has requested, which includes, among other things, unit sales, average selling prices over time, business documents and testimony from Novartis business people to establish the extent of competition in the marketplace, etc., as well as discovery from Roche concerning its pricing decisions, forecasts, and models.

Plexxikon is aware that Novartis has contended that the market that includes Tafinlar® and Zelboraf® is a broader one that includes various immunotherapies. Plexxikon will introduce evidence to show that is incorrect (including because the response rates for immunotherapies is much lower than for selective BRAF inhibitors, because the two therapies have different indications, because physicians often use selective BRAF inhibitors and immunotherapies in combination or sequence and because this means that if one selective BRAF inhibitor were not available a physician who is otherwise inclined to prescribe a BRAF inhibitor would tend to prescribe the other one rather than forgo *any* BRAF inhibitor in favor of relying solely on an immunotherapy). However, Plexxikon may also perform the above described lost royalties calculation under the assumption that the immunotherapies on which Novartis relies may be considered part of the market. Plexxikon currently lacks the information necessary to perform that calculation, including (a) the sales histories of those immunotherapies and (b) information showing that there is any substitution going on the market between selective kinase inhibitors and immunotherapies, including business documents and testimony from Novartis business people to establish the extent of competition.

**B. Additional Information Needed**

In order to provide a fulsome response, Plexxikon needs, in addition to the information mentioned above:

1. Analyses of the extent to which Tafenlar® has expanded the market for BRAF kinase inhibitors.
2. Market shares for each product.
3. Documents from Novartis and Roche, as well as industry reports, indicating the extent of competition between Tafenlar®, Zelboraf®, and other drugs.
4. Studies, reports, or analyses indicating factors that influence the physician or customer demand for Tafenlar® and Zelboraf® including, but not limited to:
  - a. Incidence of disease;
  - b. Efficacy of treatment;
  - c. Tolerability of treatment (side effects);
  - d. Competition from other treatments (e.g. chemotherapy, immunotherapy);
  - e. Any other factors that influence the decision to prescribe or purchase one selective BRAF inhibitor over another or over any other option.
5. Roche documents concerning the actual prices of Zelboraf®, including any price changes over time and any analyses of competitive effects from Tafenlar®.
6. Unit sales and prices of Tafenlar®, Mekinist®, and other relevant products over time by indication and NDC code (or sufficient information to determine the package volume and dosage).
7. Estimates of the percentage of Tafenlar® and Zelboraf® sales that are for metastatic melanoma, or the percentage of sales that are used off label.

**III. PRICE EROSION**

Plexxikon intends to establish that the presence of the accused product subsequent to the date of first infringement has resulted in price erosion. Plexxikon will perform this calculation by analyzing price histories and reviewing business documents. In order to perform this calculation, Plexxikon needs financial information it has requested from Novartis in discovery, including the unit sales of products in the relevant market and their average selling price over time, as well as business documents and

1 testimony from business people, as well as discovery from Roche regarding pricing, modeling of the  
2 market, and testimony from business people, and the other information listed above.

3  
4 Dated: April 9, 2018

DURIE TANGRI LLP

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